REMARKS

Reconsideration of this application, as amended, is respectfully requested.

I. Status of the Claims

Claims 20-31 are pending.

Claims 21-22 have been canceled.

Claims 20 and 23 have been amended with no new matter added. Support for the amendments can be found, for example, in original claim 22.

II. Amendments to the Specification

The Examiner objected to the Specification for page 12 allegedly containing markings. A clean substitute page 12 is attached, copied from our file. The Specification has also been amended to update the status of the lineage of this application. No new matter has been added.

III. Double Patenting Rejection

Claims 20-23, 27 and 28 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 20-23, 25, 28 and 29 of U.S. Patent No. 6,066,309. The Examiner states that while the claims are not identical, the claims differ in that the instant invention specifically states that the composition al product is a kit.

Applicants note that U.S. Patent No. 6,066,309 contains only claims 1-4 and does not contain any claims numbered 20-23, 25, 28 and 29. Applicants proceed on the

assumption that the Examiner intended the rejection to be over claims 1-4 of U.S. Patent No. 6,066,309.

In response, a Terminal Disclaimer is filed, disclaiming the term of any patent which exceeds beyond the term of U.S. Patent No. 6,066,309. This disclaimer is being submitted to expedite prosecution without conceding the correctness of the Examiner's position.

IV. Rejections Under 35 U.S.C. § 112. First Paragraph

The Examiner has rejected claims 20, 21 and 24-31 under 35 U.S.C. § 112, first paragraph, as not enabled by the Specification. The Examiner indicates that while the Specification is enabling for kits wherein the partially reduced protein is an anti-SSEA-1 IgM monoclonal antibody, the Specification does not reasonably provide enablement for all partially reduced protein.

This rejection has been rendered moot because claim 20, as presently amended, is limited to an anti-SSEA-1 IgM monoclonal antibody.

V. Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 20, 21 and 24-31 under 35 U.S.C. § 112, second paragraph, as indefinite. The Examiner contends that one cannot ascertain what is being claimed because the claims read on a multitude of possible proteins.

This rejection has been rendered moot by the present amendment. Applicants respectfully request the Examiner withdraw both rejections of the claims under 35 U.S.C. § 112.

VI. Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 20, 21 and 24-31 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,510,125 to Grogg et al. ("Grogg"). The Examiner contends that Grogg discloses compositions that are useful for making imaging kits comprising a tissue specific carrier and a stannous compound. The Examiner further contends that the following ingredients may also be present in the composition Tc-99m, a stabilizer, stannous ion and a tumor specific antibody. The Examiner admits, however, that Grogg does not disclose a specific example having all the components set forth in the present claims. However, the Examiner contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit comprising a protein, stannous ion, stabilizer based on the disclosure of Grogg.

Applicants respectfully traverse the rejection and submit that the present claims, as amended, are not obvious in view of Grogg. Claim 20 has been amended to clarify that the protein is an anti-SSEA-1 IgM monoclonal antibody. As noted by the Examiner, the prior fails to render obvious this protein, labeled and in combination with stannous ion, and ascorbic acid and water soluble salt, esters and mixtures thereof.

Therefore, Grogg fails to render the present claims obvious. Applicants respectfully request the Examiner withdraw the rejection to the claims.

VII. Conclusion

In view of the action taken and arguments made, it is believed the rejections to claims 20-31 have been overcome. Claims 20, and 23-31 are now believed to be in condition for allowance.

Favorable action is earnestly solicited.

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Respectfully submitted,

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thereof then added to the radiolabeled protein or peptide in the radiolabeling vial. The amount and molar concentration of ascorbic acid added will depend on the formulation, the desired dose volume, the type of radioisotope, and the quantity of radiation. Commercially available compositions containing ascorbic acid (or a derivative) may be used, typically containing 500 mg/2 ml ascorbic acid, with the volume added ranging from 10 μl to 2 ml, and preferably from 250 μl to 1 ml. The derivative may be a physiologically acceptable water soluble salt of ascorbic acid, such as sodium ascorbate, potassium ascorbate, lithium ascorbate, etc. or ester of ascorbic acid. When a derivative of ascorbic acid is employed, an equivalent amount (on a molar basis) is used.

Once the stabilizing agent is added to the radiolabeled protein or peptide, the composition may be prepared for administration. Typically, the radiolabeled composition is administered parenterally, and most commonly intravenously, but other forms of administration are contemplated and possible.

Preferably, the stabilizer of the invention is added as soon as radiolabeling is complete. If any purification of the radiolabeled protein is necessary, the stabilizer can be added after such purification. It is an advantage of the invention, however, that incorporation of the stabilizer in compositions containing excess stannous ion prevents formation of quantities of stannous colloids and other radiochemical impurities that would interfere with performance of the radiolabeled protein or peptide for its intended imaging diagnostic or therapeutic purpose.

The invention is further illustrated by the following non-limiting examples.

EXAMPLE 1 - PREPARATION OF A STABILIZED RHENIUM-LABELED RC-160 PEPTIDE-BASED RADIOPHARMACEUTICAL COMPOSITION

RC-160 is a cyclic somatostatin analogue with the general structure:

D-Phe-Cys-Tyr-D-Trp-Lys-Val-Cys-Trp-NH2

Radiolabeling kits were prepared using aseptic techniques, with each kit prepared in a 10 ml serum vial using a 2 ml liquid fill. The liquid fill contained 200 μg of RC-160